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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/296,040	04/21/99	DANEK	C 031201-025

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QM12/0817

EXAMINER

FARAH, A

ART UNIT

PAPER NUMBER

3739

DATE MAILED:

08/17/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
09/296,040

Applicant(s)

Danek et al.,

Examiner

Ahmed Farah

Group Art Unit

3739



☐ Responsive to communication(s) filed on \_\_\_\_\_

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 1-54 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-6, 11-13, 41, 42, and 45-54 is/are rejected.

☒ Claim(s) 7-10, 14-40, 43, and 44 is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4&5

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Art Unit: 3739

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

2. Claims 1-3, 5, 41, and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by Magovern (U.S. Pat. No. 5,979,456). Magovern discloses a method and apparatus for reversibly modifying the shape of a selected portion of the body such as the pharynx, to produce a desired result, for example, to overcome obstructive sleep apnea by urging open the pharynx. Magovern's apparatus can include an energy source coupled to a preconfigured structure for providing activation energy, responsive to a predetermined stimulus, wherein said energy source can be an electrical, mechanical, thermal, electromagnetic, or a combination thereof. See Magovern, Col. 2 line 66 through Col. 3 line 1. Further, Magovern teaches that his apparatus can be used external to, or internal within, the body. In reference to claim 5, Magovern teaches that the energy transfers alters the airway in such a manner that the ability of the airway to narrow is reduced. See Magovern Col. 2, line 31-40.

Art Unit: 3739

3. Claims 1-3, 5, 11, 12, 41, 42, and 45-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Ellman et al (U.S. Pat. No. 5,505,728). Ellman discloses an electrode for use in electrosurgical procedure to improve to improve snoring and sleep apnea. Ellman teaches a procedure of reducing snoring or sleep apnea by electrosurgically stripping layers of tissue of the wide lateral pharyngell walls and low arched soft palate on both sides of the uvula, said procedure being carried out via the oral cavity of the patient while sparing the uvula. Ellman's procedure alters the structure of the airway wall by decreasing the thickness of the airway wall, thus inherently treating the conditions of the lungs by decreasing airway resistance to airflow. See Fig. 4 of Ellman.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Magovern in view of Wiggs et al., "On the mechanism of mucosal folding in normal asthmatic airways", The American Physiological Society, 0161-7569/97. Magovern has been described above. However, although Magovern's energy transfers alters the airway in such a manner that the ability of the

Art Unit: 3739

airway to narrow is reduced, he does not teach a method of treating asthma by preventing the contraction of the airways. Wiggs simulates the effect of smooth muscle shortening and also describes its effect on airway walls, as seen in asthma patients. In a detailed discussion, Wiggs teaches that the narrowing of the airways may cause airflow obstructions, thereby making it difficult for asthma sufferers to breath. Therefore, it would have been obvious to one having the ordinary skill in the art at the time of the applicant's invention to modify Magovern's invention in view of Wiggs and prevent the narrowing of the airways in order to relief asthma patients from breathing difficulties.

6. Claims 6, 13, and 50-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ellman et al., (U.S. Pat. No. 5,505,728) in view of Edwards et al., (U.S. Pat. No. 5,624,439) and Hovda et al., (U.S. Pat. No. 6,053,172). However, Ellman, described above, does not teach a method for treating airway by moving energy transfer device along the airway.

Edwards discloses a method and apparatus for treatment of airway obstructions comprising a first arm including a proximal end and a distal end, the first arm distal end is inserted into the throat and positioned adjacent to a back surface of the tongue. Edwards further teaches that a plurality of RF electrodes are positioned in the first arm wherein said electrodes are advanced into the back of the tongue in order to ablate a selected area of the back of said tongue.

Hovda discloses a system and method for selectively applying electrical energy to a target location within the head and neck of a patient's body, particularly including tissue in the ear, nose, and throat. In addition, Hovda teaches that a high frequency electrical energy, applied to one or more

Art Unit: 3739

electrode terminals, is used to modify the tissue structure. See Fig. 14 of Hovda. Hovda also teaches that his invention is particularly useful for removing occlusive media within a small body passages.

Therefore, it would have been obvious to one having the ordinary skill in the art at the time of the applicant's invention to modify Ellman's procedure in view of Edwards and in view of Hovda and move the energy transfers device along the airway in order to reduce tissue inflammation, and alter the function of the airway wall by altering the resting tone of the airway wall.

***Allowable Subject Matter***

7. Claims 7-10, 14-40, 43, and 44 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Art Unit: 3739

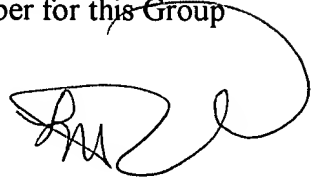
*Conclusion*

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See the following references:

- |                    |                         |
|--------------------|-------------------------|
| 1. DiMarco         | U.S. Pat. No. 5,991,218 |
| 2. DiMarco         | U.S. Pat. No. 5,678,535 |
| 3. Vince           | U.S. Pat. No. 5,056,519 |
| 4. Geddes et al.,  | U.S. Pat. No. 4,827,935 |
| 5. Borkan          | U.S. Pat. No. 4,612,934 |
| 6. Vince           | U.S. Pat. No. 5,265,604 |
| 7. Fairfax et al., | U.S. Pat. No. 5,634,471 |
| 8. Xu et al.,      | U.S. Pat. No. 5,699,799 |
| 9. DiMarco         | U.S. Pat. No. 5,999,855 |

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. Farah whose telephone number is (703)305-5787.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Linda Dvorak, can be reached on (703) 308-0994. The fax number for this Group is (703)305-3590.



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